UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/551,380	04/18/00	CHANG	D MLY-5

HM22/0718

DORITY & MANNING PA
ATTN: JUDY C JARECKI-BLACK PHD
P O BOX 1449
GREENSVILLE SC 29602-1449

EXAMINER	
FRONDA, C	
ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/551,380	Applicant(s) Chang et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-27 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 25, and 26, drawn to a fluorescent protein, classified in class 530, subclass 350.

II. Claims 8-10, drawn to nucleic acid, recombinant DNA construct, a host cell transformed with said recombinant DNA construct, classified in class 435, subclass 252.3.

III. Claims 11,12, and 21, drawn to a method for determining protease activity in a sample cell transformed or transfected with a recombinant DNA construct comprising a nucleic acid sequence encoding a modified fluorescent protein, classified in class 435, subclass 7.4.

IV. Claim 13, drawn to a method for detecting a change in protease activity in a sample cell transformed or transfected with a recombinant DNA construct comprising a nucleic acid sequence encoding a modified fluorescent protein, classified in class 435, subclass 7.4.

V. Claim 14, drawn to a method for determining the effect of a compound on the activity of a protease in a cell transformed or transfected with a recombinant DNA construct comprising a nucleic acid sequence encoding a modified fluorescent protein, classified in class 435, subclass 23.

VI. Claim 15, drawn to a method for determining the effect of a compound on the activity of a protease in first and second cells transformed or transfected with a recombinant DNA construct comprising a nucleic acid sequence encoding a modified fluorescent protein, classified in class 435, subclass 23.

VII. Claims 16, 17, and 22, drawn to a method for determining protease activity in a sample comprising adding a modified fluorescent protein to said sample, classified in class 435, subclass 7.72.

VIII. Claim 18, drawn to a method for detecting a change in protease activity in a sample comprising adding a modified fluorescent protein to said sample, classified in class 435, subclass 7.72.

IX. Claims 19 and 23, drawn to a method for determining the effect of a compound on the activity of a protease in a sample comprising adding a modified fluorescent protein to said sample, classified in class 435, subclass 23.

X. Claim 20, drawn to a method for determining the effect of a compound on the activity of a protease in first and second samples comprising adding a modified fluorescent protein to said sample, classified in class 435, subclass 23.

XI. Claim 24, drawn to a method of using a modified fluorescent protein to determine the effect of first and second compounds on the activity of a protease, classified in class 435, subclass 23.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The polypeptide of Group I and the polynucleotide of Group II are independent chemical entities and require different literature searches.

The invention of Group I is unrelated to the inventions of Groups III-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups III-VI do not require the product of Group I.

The invention of Group II is unrelated to the inventions of Groups VII-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups VII-XI do not require the product of Group II.

The invention of Group I is related to the inventions of Groups VII-XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the protein in a process for producing antibodies against the protein.

The invention of Group II is related to the inventions of Groups III-VI as product and

process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the cell transformed or transfected with a recombinant DNA construct encoding a fluorescent protein in a process for expressing, producing, and isolating large quantities of the fluorescent protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Claims 5, 6, and 7 generic to a plurality of disclosed patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

For claims 5 and 6, the species are D9, MD9, D4, D7, D8, E2, E3-1, E3-5, E3-9, E3-12, E4-a, E4-g, E4-j, E4-o, E4-p, BFP, CFP, YFP, and DsRed.

For claim 7, the species are SEQ ID Nos: 4 and 7-13.

If Group I is elected, then Applicants are required to elect only one protein species selected from the group consisting of D9, MD9, D4, D7, D8, E2, E3-1, E3-5, E3-9, E3-12, E4-a, E4-g, E4-j, E4-o, E4-p, BFP, CFP, YFP, and DsRed. Furthermore, if Group I is elected, then applicants are required to elect only one species of SEQ ID Nos: 4 and 7-13.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

6. The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. The amino acid sequences of each of the proteins D9, MD9, D4, D7, D8, E2, E3-1, E3-5, E3-9, E3-12, E4-a, E4-g, E4-j, E4-o, E4-p, BFP, CFP, YFP, and DsRed (claims 5 and 6) which are critical or essential to the practice of the invention have not been disclosed in the application.

Applicants must provide a paper copy of the "Sequence Listing" of the proteins, a computer readable form (CRF) copy of the "Sequence Listing" of the proteins, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d) (see attached "Notice to Comply with Requirements for Patent Applications containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures").

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/551,380	4/18/2000	Chang et al.	MLY-5

EXAMINER	
Christian Fronda	
ART UNIT	PAPER NUMBER
1652	6

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. The amino acid sequences of each of the proteins D9, MD9, D4, D7, D8, E2, E3-1, E3-5, E3-9, E3-12, E4-a, E4-g, E4-j, E4-o, E4-p, BFP, CFP, YFP, and DsRed (claims 5 and 6) which are critical or essential to the practice of the invention have not been disclosed in the application.

APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication should be directed to Examiner Christian Fronda, Art Unit 1652, whose telephone number is (703)305-1252.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703)308-0196.

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY